(iii) The number of units of finished form used in the compound, the number compounded and the number lost during compounding, with the causes for such losses, if known; and

(iv) Such other information as is necessary to account for all controlled substances used in the compounding process;

(7) The number of containers distributed to other programs, including the date, the number of containers in each distribution, and the name, address and registration number of the program to whom the containers were distributed;

(8) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(9) The number of units of finished forms and/or commercial containers destroyed in any manner by the registrant, including the reason, the date and manner of destruction. All other destruction of narcotic controlled substances will comply with § 1307.22.

[39 FR 37985, Oct. 25, 1974]

REPORTS

§ 1304.31 Reports from manufacturers importing opium.

(a) Every manufacturer importing crude opium shall submit, in addition to the report on DEA (or BND) Form 234 and its supplements, DEA (or BND) Form 247 and its supplements, 247a and 247b, accounting for the importation and for all manufacturing operations performed between importation and the production in bulk of finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary, or other recognized medical standards. Subsequent manufacture from such products, including bottling or packaging operations, shall be accounted for in the quarterly returns on DEA (or BND) Form 234 and its supplements. DEA (or BND) Form 247 and its supplements shall be submitted quarterly to the Drug Control Section, Drug Enforcement Administration, Department of Justice, Washington, DC 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The report of manufacture from crude opium shall consist of summaries (DEA (or BND) Forms 247 and 247a) with supporting detail sheets (on DEA (or BND) Form 247b) accounting for original manufacture from crude opium, production from morphine for further manufacture and production from manufacturing opium, and also accounting for stocks of crude opium, manufacturing opium, morphine for further manufacture and other crude alkaloids.

(c) The detail sheets (DEA (or BND) Form 247b) supporting the summary of original manufacture from crude opium shall show separately the crude opium used for the manufacture of opium tinctures and extracts, crude opium used for the extraction of alkaloids, crude opium used for the manufacture of controlled substances listed in Schedule V, and crude opium used for the production of manufacturing opium; and shall show separately the medicinal opium, alkaloids and salts, opium tinctures and extracts, controlled substances listed in Schedule V, and manufacturing opium produced.

(d) Importation of opium shall be reported in summarized entries in the debit summary of the quarterly report (DEA (or BND) Form 234) and shall be immediately reported by similar summarized entries in the credit summary of the quarterly report (DEA (or BND) Form 234) as transferred to importing manufacturer's report. Such importations shall further be reported in summary (DEA (or BND) Form 247) and supporting detail sheets (DEA (or BND) Form 247b). Products manufactured therefrom shall be reported as produced in accordance with paragraphs (b) and (c) of this section and, with the exception of manufacturing opium, morphine for further manufacture, and other crude or unfinished alkaloids, shall be transferred to the quarterly report (DEA (or BND) Form 234) when reported produced.

(e) Upon importation of crude opium, samples will be selected and assays made by the importing manufacturer in the manner and according to the

method specified in the U.S. Pharmacopoeia. These assays shall be accounted for in terms of its anhydrous morphine alkaloid content. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(f) Upon withdrawal of crude opium from customs custody, the importing manufacturer shall assign to each container an identification mark or number by which the opium will be associated with the lot assay and identified in reports.

(g) Where factory procedure is such that partial withdrawals of opium are made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.

(h) Opium products and derivatives which are produced for exclusive use in further manufacturing purposes shall be reported produced when they come into existence in that form in which they are to be so used. Medicinal opium, morphine and its salts, or other alkaloids or derivatives produced exclusively for distribution shall be reported as produced when manufacture has actually been completed and the finished marketable product ready for packaging and distribution. Such products shall be regarded as ready for packaging and distribution as soon as all processing other than mere packaging has been completed. Medicinal opium, tinctures, extracts, or other products manufactured partly for distribution and partly for use in further manufacture will be reported produced as soon as manufacture is complete and they are ready either for use in further manufacture or for packaging for distribution.

(i) Subject to §1303.24(c) of this chapter, no accumulations of morphine or other narcotic controlled substances in their pure or near-pure states shall be permitted to remain inactively in process for an unreasonable time in light of efficient industrial practices. All such products nearing completion of their respective processes and approaching a condition of purity shall be carefully protected, promptly completed, and immediately transferred to finished stocks, and reported as produced.

(j) In making conversions of opium alkaloids and their salts to anhydrous morphine the quantity of the particular alkaloid or salt in avoirdupois ounces shall be multipled by a conversion factor arrived at by ascertaining the ratio, carried to the fourth decimal place, between the respective molecular weight of such alkaloid or salt and the molecular weight of anhydrous morphine (285.16), such weights being computed to the third decimal place from the chemical formulae of the substances and the atomic weights of elements, as adopted by the International Committee on Chemical Elements and published in the latest edition of the U.S. Pharmacopoeia.

[36 FR 7794, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973. Redesignated and amended at 51 FR 5319, 5320, Feb. 13, 1986]

§ 1304.32 Reports of manufacturers importing medicinal coca leaves.

(a) Every manufacturer importing raw coca leaves for the manufacture of medicinal products shall submit, in addition to the report on DEA (or BND) Form 234 and its supplements, DEA (or BND) Form 168 and its supplements, 168a and 168b, accounting for the importation and for all manufacturing operations performed between the importation and the manufacture of bulk or finished products standardized in accordance with U.S. Pharmacopoeia, National Formulary, or other recognized standards. Subsequent manufacture from such products, including bottling or packaging operations, shall be accounted for in quarterly reports on DEA (or BND) Form 234 and its supplements. Reports on Form 168 and its supplements shall be submitted quarterly to the Drug Control Section, Drug Enforcement Administration, Department of Justice, Washington, DC 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The report of manufacture from medicinal coca leaves shall consist of summaries (DEA (or BND) Forms 168 and 168a) with supporting detail sheets (DEA (or BND) Form 168b) accounting for original manufacture from such